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| 09/998,733 | 11/30/2001 | Rud Istvan | 05123.00004 | 7816 |

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| EXAMINER | |
|---|---|
| GREENE, DANA D | |
| **ART UNIT** | **PAPER NUMBER** |
| 3762 | |

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/998,733 | ISTVAN ET AL. | |
| | Examiner | Art Unit | |
| | Dana D. Greene | 3762 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-33,35-39,41-49,51-64 and 66-104 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-33, 35-39, 41-49, 51-64, and 66-104 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

**Drawings**

1. In view of the response filed on September 14, 2004, the Examiner has withdrawn the objection to the drawings under 37 C.F.R §1.83 (a).

**35 U.S.C §101**

2. In view of the response filed on September 14, 2004, the Examiner has withdrawn the rejection of claims 43-44 and 38-39 under 35 U.S.C. §101.

**35 U.S.C. §112**

3. In view of the response filed on September 14, 2004, the Examiner has withdrawn the rejection of claims 82, 83, 96, and 97 under 35 U.S.C. §112.

**Claim Rejections – 35 U.S.C. §102**

4. Claims 47, 50, and 51 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by Price (U.S. Patent No. 6,141,575, hereinafter "Price"). The Examiner has given full consideration to the Applicants' response filed on September 14, 2004. Unfortunately, Applicants' amendment of claim 47 does not overcome this rejection.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

In making this rejection, the Examiner asserts that Price clearly anticipates claims 47, 50, and 51 by disclosing an electrode assembly that has an underlying

adhesive layer secured to the non-conductive pad and a removable backing strip (*see* abstract, Price). Further, Price teaches the adhesive found on the underside of at least some of the individual non-conductive pads (*see* col. 5, ln. 32-33, Price). The addition of the dielectric material does not overcome the rejection because that material is merely another non-conductive material. Finally, Examiner notes the cancellation of claim 50.

5. In view of the response filed on September 14, 2004, the Examiner has withdrawn the rejection of claims 66-68 and 70-73 under 35 U.S.C. §102(b).

**Claim Rejections – 35 U.S.C. §103**

6. The Examiner has fully considered the arguments made by the Applicants. However, such arguments are not persuasive and claims 1, 4, 9-12, 19, 26, 85-88, 92-95, and 98 remain rejected under 35 U.S.C.§103(a) as being unpatentable over Segalowistz (U.S. Patent No. 5,307,818, hereinafter "Segalowistz").

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

When considering this rejection, it is important to note that the object of Segalowistz is to provide an electrocardiographic and monitoring system in which the physical wires between the patient and the electrocardiograph or monitor are eliminated

(*see* col. 4, ln. 51-54. Segalowistz). This reference clearly discloses the wireless monitoring system of the claimed invention, except for the terminals and the user interface on the base station (*see* col. 5, ln. 8-21, Segalowistz). However, it would have been obvious to one of ordinary skill in the art to use connectors to attach the s3 leads to the monitor since it is one well known method of attaching electrical wires. In this connection, to add signal lights to the base to indicate whether the base unit is receiving transmission would have also been obvious given Segalowistz's teaching of this feature to inform the user that the device is operating properly (*see* col. 5, ln. 26-31, Segalowistz). Finally, Segalowistz does disclose the transmission of signals to an electrocardiograph monitor at column 5 lines 23-26.

7. Claims 2, 3, 20, 89, 90, 96, 97, and 99-104 also remain rejected under 35 U.S.C. §103(a) as being unpatentable over Segalowistz in view of either Olejniczak (U.S. Patent No. 6,150,951, hereinafter "Olejniczak") or De La Huerga (U.S. Patent No. 6,139,495, hereinafter "De La Huerga"). Segalowistz is considered to disclose the claimed invention as discussed above. As illustrated in the embodiments of Figure 18, the device includes ECG sensors (361), a wireless transmitter (372) and a receiving base station that attaches to a display. Segalowistz teaches the feeding of the output directly to a monitor (*see* col. 11, ln. 1-11, Segalowistz) through 3 input leads as illustrated in Figure 1a. Further, Segalowistz discloses the addition of signal lights to the sensors to indicate whether an output is being recorded (*see*, Figure 12a, Segalowistz).

Therefore, Segalowistz is considered to disclose the claimed invention as discussed above, except for the terminals, the user interface on the base station, and the token key recited in claims 2 and 3. Olejniczak teaches the use of token keys to pair the base unit to the transmitter (*see* col. 3, ln. 62-66, Olejniczak).

As stated in the non-final office action, it would have been obvious to one of ordinary skill in the art to add token keys to the base station given the teachings of either Olejniczak or De La Huerga that this feature assures that the base station is recording the proper signal. These prior art references contain suggestion that they be combined in the manner suggested. It would also have been obvious to one of ordinary skill in the art to use connectors to attach the 3 leads to the monitor since it is one well-known method of attaching electrical wires. Finally, to add signal lights to the base to indicate whether the base unit is receiving transmission would have also been obvious given Segalowistz's teaching of this feature to inform the user that the device is operating properly.

8. Claims 5, 6, and 84 remain rejected under 35 U.S.C. §103(a) as being unpatentable over Segalowistz in view of Minoz (U.S. Patent No. 6,115,622, hereinafter "Minoz").

Segalowistz discloses a wireless monitoring system. As illustrated in the embodiments of Figure 18, the device includes ECG sensors (361), a wireless transmitter (372) and a receiving base station that attaches to a display. Segalowistz teaches the feeding of the output directly to a monitor (*see* col. 11, ln. 1-11, Segalowistz) through 3 input leads as illustrated in Figure 1a. Further, Segalowistz

discloses the addition of signal lights to the sensors to indicate whether an output is being recorded (*see*, Figure 12a, Segalowistz).

Segalowistz discloses all of the limitations of claims 5, 6, and 84 except for the terminals, the user interface on the base station and the removable body unit. However, Minoz teaches a sensor that records medical data (*see* col. 1, ln. 5-10, Minoz). The system includes a body electronic unit that is connected to the chest assembly making the device interchangeable, removable, and easier to use and operate (*see* col. 2, ln. 36-52, Minoz). Given Minoz's teaching, it would have been obvious to one of ordinary skill in the art to make the body electronic unit in Segalowistz's device independent of the sensors and removable to make the components removable, interchangeable, and easier to use. To add a surge protector to a signal conditioner 21 would have been obvious to one of ordinary skill in the art since it is desirable to protect the delicate equipment. It would also have been obvious to one of ordinary skill in the art to use connectors to attach the 3 leads to the monitor since it is a well-known method of attaching electrical wires. Finally, the addition of signal lights to the base to indicate whether the base unit is receiving transmission would have been obvious given Segalowistz's teaching of this feature to inform the user that the device is operating properly.

9. Claim 7 remains rejected under 35 U.S.C. §103(a) as being unpatentable over Segalowistz in view of Minoz as applied to claim 5 above, and further in view of Olejniczak or De La Huerga.

Olejniczak teaches the use of token keys to pair the base unit to the transmitter (*see* col. 3, ln. 62-66, Olejniczak). As stated in the non-final office action, it would have been obvious to one of ordinary skill in the art to add token keys to the base station given the teachings of either Olejniczak or De La Huerga that this feature assures that the base station is recording the proper signal.

10. Claim 8 remains rejected under 35 U.S.C. §103(a) as being unpatentable over Segalowistz in view of Minoz as applied to claim 5 above, and further in view of Olson (U.S. Patent No. 5,645,571, hereinafter "Olson"). Olson discloses a defibrillator having a cradle that is used to store components of the device (*see* col. 2, ln. 23-27, Olson). This prevents elements from being lost or misplaced when the system is not in use. Given this teaching by Olson, it would have been obvious to one of ordinary skill in the art to add a cradle to the system of Segalowistz and Minoz to prevent components from being lost.

11. Claim 13 remains rejected under 35 U.S.C. §103(a) as being unpatentable over Segalowistz in view of Olson. Olson discloses a defibrillator having a cradle that is used to store components of the device (*see* col. 2, ln. 23-27, Olson). This prevents elements from being lost or misplaced when the system is not in use. Given this teaching by Olson, it would have been obvious to one of ordinary skill in the art to add a cradle to the system of Segalowistz to prevent components from being lost.

12. Claim 14 remains rejected under 35 U.S.C. §103 (a) as being unpatentable over Segalowistz in view of Minoz as applied to claims 5 and 6 above in further view of Price.

Price teaches an ECG having a precordial overlay and electrodes that are

removably coupled to a monitor through removable cables (*see* col. 1 ln. 10-15, Price). This allows the assembly to be quickly and easily positioned. Given this teaching it would have been obvious to one of ordinary skill in the art to use removable cables with the precordial overly and electrodes to make the device of the proposed combination easier to position.

13. Claims 15-17 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Segalowistz in view of Minoz and Price as applied to claim 14 above in further view of Olejniczak.

Olejniczak teaches the use of token keys to pair the base unit to the transmitter (*see* col. 3, ln. 62-66, Olejniczak). As stated in the non-final office action, it would have been obvious to one of ordinary skill in the art to add token keys to the base station given the teachings of Olejniczak that this feature assures that the base station is recording the proper signal.

14. Claim 18 remains rejected under 35 U.S.C. §103(a) as being unpatentable over Segalowistz in view of Minoz and Price as applied to claim 14 above in further view of Olson. Olson discloses a defibrillator having a cradle that is used to store components of the device (*see* col. 2, ln. 23-27, Olson). This prevents elements from being lost or misplaced when the system is not in use. Given this teaching by Olson, it would have been obvious to one of ordinary skill in the art to add a cradle to the system of Segalowistz, Minoz, and Price to prevent components from being lost.

15. Claims 21, 22, 24, and 27 remain rejected under 35 U.S.C. §103(a) as being unpatentable over Minoz in view of Delvin.

Minoz discloses a device for transmitting a wireless signal to a monitor. The system includes a body electronic unit and a connector assembly. However, Minoz does not disclose the system that turns on the device when a connection is detected. Delvin discloses an electrode assembly (*see* col. 1, ln. 61-66, Delvin). The device includes a system that turns on the device when the connection is detected (*see* col. 1, ln. 61 – col. 2, ln. 5, Delvin). To add controls that turn the device on when connections are made between the cables and transmitter in Minoz's device would have been obvious in view of Delvin.

16. Claims 23 and 25 remain rejected under 35 U.S.C. §103(a) as being unpatentable over Minoz in view of Delvin as applied to claim 21 in further view of Olejniczak or De La Huerga.

Both Olejniczak and De La Huerga teach the use of token keys to pair the base unit to the transmitter. More specifically, Olejniczak teaches the use of token keys to pair the base unit to the transmitter (*see* col. 3, ln. 62-66, Olejniczak). As stated in the non-final office action, it would have been obvious to one of ordinary skill in the art to add token keys to the base station given the teachings of either Olejniczak or De La Huerga that this feature assures that the base station is recording the proper signal.

17. Claims 28, 55-63, and 76 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Delvin in view of Price.

Delvin discloses an electrode assembly (*see* col. 1, ln. 61-66, Delvin). The device includes a system that turns on the device when the connection is detected (*see* col. 1, ln. 61 – col. 2, ln. 5, Delvin). This is equivalent to the activation of the signals

upon completion of a circuit formed between the body electronics unit and the connector as disclosed in the newly amended claim 28. Delvin does not disclose the electrode retaining section. However, Price discloses an electrode assembly having a precordial overlay that helps position the sensors quickly and accurately (*see* col. 1 ln. 10-15, Price). It would have been obvious to one skilled in the art to combine the teachings of Delvin with the precordial overlay of Price to help position the electrodes quickly and accurately.

18. Claims 29-37 and 54 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Delvin in view of Price as applied to claim 28 above in further view of Segalowistz.

When considering this rejection please note that Segalowistz teaches an electrode assembly having expandable section allowing the device to be adapted to different size patients (*see* abstract, Segalowistz). Given this teaching by Segalowistz, it would have been obvious to one of ordinary skill in the art to add expandable sections to the overlay of the proposed combination to make the device adaptable to different size patients.

19. Even though Applicants have presented arguments for claims 38-46 and amended claim 43, claims 38-46 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Delvin in view of Price as applied to claim 28 above in further view of Etters (U.S. Patent No. 6,010,359, hereinafter "Etters").

Etters discloses a coupling having spring flanges to help secure the elements

together (*see* col. 3, ln. 58-62, Etters). Given this teaching by Etters, it would have been obvious to one of ordinary skill in the art to add spring flanges to the connection of the proposed combination to help secure the connection together.

20. Claims 47-51 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Price. It is considered obvious to attach the device to some form of connector. To make the shielding in an x pattern rather than a rectangular pattern to reduce the material used in it's construction would have been obvious to one of ordinary skill in the art.

21. Claims 52, 53, 64, 65, 69, 74, and 77-79 remain rejected under 35 U.S.C. §103(a) as being unpatentable over Delvin in view of Price as applied to claims 28 and 55 above further in view of Minoz. Based on Applicant's amendments, claims 66-68 and 70-73 also stand rejected under 35 U.S.C. §103(a) as being unpatentable over Delvin in view of Price as applied to claims 28 and 55 above further in view of Minoz. Minoz discloses a device for transmitting a wireless signal to a monitor (*see* col. 1 ln. 10-20, Minoz). The system includes a body electronic unit and a connector assembly. Given the teachings of Minoz, it would have been obvious to one of ordinary skill in the art to ad a wireless transmitter to the device of the proposed combination to reduce the number of cables between the patient and the monitor.

22. Claims 75 and 81 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Delvin in view of Price and Minoz as applied o claims 69 74 above in further view of either Olejniczak or De La Huerga.

Both Olejniczak and De La Huerga teach the use of token keys to pair the base unit to the transmitter. For example, Olejniczak teaches the use of token keys to pair the base unit to the transmitter (*see* col. 3, ln. 62-66, Olejniczak). This assures that the proper signal is received and matched. It would have been obvious to one of ordinary skill in the art to add token keys to the base station of the proposed combination given either Olejniczak and De La Huerga teaching that this feature assures that the base station is recording the proper signal.

With regard to claim 81, Olejniczak teaches using tongues and grooves with the token key.

23. Claim 80 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Delvin in view of Price and Minoz as applied to claim 69 and 74 above in further view of De La Huerga.

De La Huerga teaches securing a transmitter to the wearers arm (*see* col. 7, ln. 9-12, De La Huerga). Given this teaching, it would have been obvious to secure the transmitter of the proposed combination to an armband to provide an assemble that is easy to position.

24. Claim 91 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Segalowistz in view of Olejniczak or De La Huerga as applied to claim 89 in further view of Olson. Olson discloses a defibrillator having a cradle that is used to store components of the device (*see* col. 2, ln. 23-27, Olson). This prevents elements from being lost or misplaced when the system is not in use. Given this teaching by Olson, it

would have been obvious to one of ordinary skill in the art to add a cradle to the system of the proposed combination to prevent components from being lost.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana D. Greene whose telephone number is (571) 272-7138. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Dana D. Greene

George Manuel

Primary Examiner